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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,940	09/05/2003	Tetsu Yamaguchi	011350-322	5490
21839	7590	03/16/2006		
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER JAWORSKI, FRANCIS J	
			ART UNIT 3737	PAPER NUMBER

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/654,940

Applicant(s)

YAMAGUCHI ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the observation part" in lines 5 and 7. There is insufficient antecedent basis for this limitation in the claim since antecedent claim 1 refers to an observation portion and an extending lumen:

the proximal side in relation to the transducer position. Jang (US5976093) or in the alternative under 35 USC103(a) as obvious based upon Jang et al in view of Leary et al (US5024234, of record with the IDS filed on 1-22-04). Jang et al teaches a rotatable and translatable ultrasound observation portion 204 and its lumen 218, first guidewire lumen 212 distal to where the ultrasound observation portion is located and in an extension line in relation to second guidewire lumen 216 on

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang et al (US5976093, of record), further in view of any one of Griffith et al (US5327885, newly of record), Pomeranz et al (US5201316, newly of record) or Shturman (US5312427, newly of record).

Jang as noted in the earlier Office action teaches a rotatable and translatable ultrasound observation portion 204 and its lumen 218, first guidewire lumen 212 distal to where the ultrasound observation portion is located and in an extension line in relation to second guidewire lumen 216 on the proximal side in relation to the transducer position. Jang does not discuss non-connectivity however whereas in Jang et al the first and second guidewire lumens share part of the catheter wall and therefore are not 'not connected to one another', it would have been obvious in view of Griffith et al 120 of figs. 1A and 6 that a distal first and proximal second lumen 106 and 120 need not be connected, meaning that 120 may terminate abruptly as a free space end-passage, and with 120 universally available to serve any of the catheter's purposes per col. 9 top, by inference including a guidewire function.

Pomeranz et al suggests in Figs. 5 – 6 that in order to make a guidewire-delivered ultrasound imaging catheter more flexible in the region of the observation portion's activity, the guidewire channel may be segmented into a different flexibility distal first lumen 60 and proximal second lumen 62, which although they are connectable (they can be integral), they can also be separately formed of differing

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materials and be joined only by virtue of shrink sleeving 70 such that relative motion of flexible lumen 60 with respect to the rest of the catheter may occur, and in this sense are adjacent but 'not connected to one another'.

Shturman may be considered as a teaching that a shape-memory extension (70 may serve in situ to variably space a first distal guidewire lumen (74, 76, 76', 76'') both longitudinally i.e. along a vessel wall and radially towards a vessel wall, which lumen is otherwise on an extension line of a second proximal guidewire lumen 24 coaxially parallel to portion 100 which serves as mount for ultrasound array 102 as an 'observation portion' when incorporated into Jang, and would remedy the 'not connected...' deficiency in Jang since the former invokes use of such alternative angioplasty tool constructs, see col. 1 lines 28 – 35 and col. 9 lines 23 – 26.

In all cases, since a planar piece is a 'part' or a 'portion', all arguments including Pomeranz-based extend to claim 10, there being no way to exclude based upon a spaced apart length whether or not the antecedence issue is present, vide supra. (Note that an 'observation part/portion' may in and of itself pertain to an exit aperture having no axial extent for example).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 - 10 as amended are further rejected under 35 U.S.C. 102(b) as being anticipated by Shturman.

Shturman notes in col. 5 lines 19-36 that since intravascular ultrasound imaging may be practiced by a rotatable ultrasound imaging guidewire since these were being developed concurrent to the patent filing, this lends to the anticipatory interpretation when applied to the construct of Figs. 13 or 28, 29, 30, since one has a movable observation portion (imaging guidewire 96) extendible with respect to the observation lumen and observation lumen in which this is disposed (100), and the first distal guidewire lumen (74,76,76',76'') and second proximal guidewire lumen 24 respectively distal and proximal to the lumen of 100 and defining the movement range of the imaging transmitter/receiver (in contradistinction to the slightly differing Shturman interpretation re three lumens supra which relies on combination with Jang).

Claims 11 – 20 are rejected under 35 U.S.C. 102(b) as anticipated by Shturman or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jang in view of Shturman.

Since in either case Shturman is relied upon as teaching spaced apart proximal and distal guidewire lumens having openings such that an extending guidewire necessarily is outside the catheter, both lines of argument carry forward as they track the respectively corresponding claims supra.

### **Response to Amendment Arguments**

Amendatory language to the base claim has mooted the prior rejection arguments.

Structure which is claimed in base claim 1 as amended is directed to the particular geometry of a catheter including an observation portion and three lumens defining passageways (since by having an extent or 'ends' they relate to passages or channels as opposed to aperture/hole), which passageways reside internal to, external to, associated with or otherwise serving as parts of the catheter with respect to guidewire and observation functions but where the observation structure and its functional cooperation are not claimed. To some extent the examiner is by the art rejections then parsing the amended claim's terms with respect to these catheter components as representing alternative interpretations in order to advance the prosecution towards patentable language exclusivity: 'Parallel' when defining the observation and guidewire lumen may mean either 'coaxial' (leading to the anticipatory argument involving Shturman where either the ultrasound imaging guidewire or the ultrasound imager are proposed to be passed along the fixed and movable guidewire lumens via a coaxially centered ultrasound imager) or it may mean 'paraxial' i.e. parallel but along side-by-side axes (all Jang-based arguments) and since applicants' specification defines the relationship between the first and second guidewire variously as 'bisected'/'spaced' and 'not connected', the amendatory language therefore embraces simply 'spaced' (Griffith added in combination), 'apposed' i.e. not spaced but not connected, i.e. abutting or end-tangent (Pomeranz et al added to combination), and 'variably spaced' (Shturman added to combination under alternative combination), all as relating to catheters having plural end-to-end aligned guidewire passageway segments functionally interacting with guidewires and ultrasound imaging observation probe components.

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Since 'spaced apart (openings)' language added to the general claim 1 combination in new base claim 11 eliminates Pomeranz, and 'external to the catheter' eliminates Griffith and Jang in combination with the former, the residuum extends as separate paraxial (Jang v Shturman) and coaxial (Shturman anticipatory) rejection arguments.


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

12-08-05

  
Francis J. Jaworski  
Primary Examiner